



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,739	09/27/2000	Brian G. Scrivens	P-5015	7708

7590

07/31/2003

Richard J Rodrick Esq
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880

EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
----------	--------------

1743

5

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS5

Office Action Summary

Application No.

09/670,739

Applicant(s)

SCRIVENS ET AL.

Examiner

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 9-12 and 15-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,454,945 to Weigl et al. (herein referred to as "Weigl").

Weigl teaches a microfluidic system comprising a plurality of inlets; means for controlling fluid flow through at least one of said inlets connected with said inlet; a laminar flow channel in fluid communication with said inlets; at least three outlets in fluid communication with said laminar flow channel; and means for controlling fluid flow through at least one of said outlets connected with said outlet (col. 7, lines 15-23). Detection and analysis is done by optical means (col. 8, lines 34-35). The apparatus may include a transparent cover plate (col. 16, lines 5-6). The input or sample stream may be any stream containing particles of the same or different size, for example blood (col. 9, lines 7-8). In a preferred embodiment, when the sample stream is whole blood, small ions diffuse rapidly across the channel, whereas larger particles diffuse slowly (col. 9, lines 16-24). The inlets need only be sized large enough to conduct the streams of parallel laminar flow (col. 10, lines 50-52). The width and depth of the inlet and outlet channels must be large enough to allow the passage of the undesired particles (col. 10, lines 63-64). In Figure 4, there is exemplified a microchannel configuration having multiple product channels to separate different sized particles.

Weigl differs from the instantly claimed invention in that it separates smaller particles from the sample stream instead of larger particles. However, Weigel teaches that the channels included therein may be modified according to the preference of the person using the device.

"The inlets and outlets may be as long, deep and wide as required for the system of which they are a part." (col. 10, lines 57-59). Thus, given this disclosure, it would have been obvious to one having ordinary skill in the art to modify the channels taught in Weigl to isolate larger particles in lieu of smaller particles if the desired end result was to capture larger particles.

Response to Arguments

3. Applicant's arguments, see Paper No. 4, filed 5/8/2003, with respect to the Parce reference have been fully considered and are persuasive. The prior rejection of claims 1 and 3-5 has been withdrawn.

4. Applicant's arguments, see Paper No. 4, filed 5/8/2003, with respect to the Columbus reference have been fully considered and are persuasive. The prior rejection of the claims has been withdrawn.

5. Applicant's arguments, see Paper No. 4, filed 5/8/2003, with respect to the rejection(s) of claim(s) 1, 2, 4-8, 13 and 14 under 35 USC 102(e) as anticipated by Weigel have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Weigl.

Applicant has asserted that in contrast to the present invention, Weigl does not disclose the use of "hardware" to achieve the separation of particles of different size and that the product of interest is of a different size. However, the Examiner would have to disagree with Applicant's

assertion regarding the lack of hardware. Clearly, Weigl teaches channels which inherently contain walls to direct the flow therein. This is certainly equivalent to the separation channels Applicant discusses on page 4, last two lines through the top of page 5. Moreover, Weigl explicitly teaches in the brief description of Figure 4 that the microchannel configuration has multiple product channels to separate different sized particles.

The Examiner agrees with Applicant's assertion that Weigl does not teach isolating larger particles within the apparatus, but as mentioned in the rejection above, it would have been obvious in light of Weigl's disclosure to modify the channel size to obtain the desired particle size.

Allowable Subject Matter

6. Claims 9-12 & 15-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a method for obtaining a liquid sample having an increased cellular or particulate concentration for optical examination wherein notches are utilized to separate larger desired particles from smaller particles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the

Application/Control Number: 09/670,739

Page 5

Art Unit: 1743

organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.



Monique T. Cole

Examiner

Art Unit 1743

MC *MC*

July 15, 2003